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EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/713,248	MATHER ET AL.	
	Examiner	Art Unit	
	Anne L. Holleran	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *2-11 and 16-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,12-15 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/04, 7/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 12-15 and 23-25, drawn to antibodies, pharmaceutical compositions comprising antibodies, hybridoma cell lines and to agents that block interaction between PIPA and a PIPA binding partner, classified in class 530, subclass 387.1 and class 424, subclass 130.1.

II. Claims 3-11, drawn to nucleic acids encoding an antibody that binds PIPA, classified in class 536, subclass 23.5.

III. Claims 16-21, drawn to methods of treatment comprising administering an anti-PIPA antibody, classified in class 424, subclass 130.1.

IV. Claim 22, drawn to methods of detecting the presence or absence of a cancer using an anti-PIPA antibody, classified in class 435, subclass 7.1.

2. The inventions are distinct, each from the other, for the following reasons:

Groups I and II are drawn to separate and distinct products. The antibodies of group I, the polynucleotides of group II are chemically distinct products unrelated in chemical structure and separately classified, having separate fields of search. The antibodies of group I have no relationship with the polynucleotides of group I. The function and existence of DNA and protein is independent of the function and existence of the other. The products of groups I and II can be independently synthesized by chemical means. Each of the products has separate, unrelated uses and is not disclosed as being capable of use together with any other products.

Further, it would place an undue burden on the examiner to examine several, independent inventions in one application.

Groups III and IV are drawn to separate and distinct processes. Group III is drawn to methods of treatment comprising delivering a chemotherapeutic agent to a cancer cell comprising administering a compositions comprising the antibody of group I. Group IV is drawn to methods of detecting the presence of a cancer cell that expressed PIPA. Thus, groups III and IV are separate and distinct methods because they comprise different method steps, and result in different endpoints. Further, it would place an undue burden on the examiner to examine several, independent inventions in one application.

Inventions I and either III or VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products of group I may be used in either the method of group III or the method of group IV, which are separate and distinct methods that are materially different processes.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Jie Zhou on 6/12/2006 a provisional election was made without traverse to prosecute the invention of Group I, claims 1, 2, 12-15 and 23-25. Affirmation of this election must be made by applicant in replying to this Office action. Claims 3-11 and 16-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even thought the requirement be traversed (37 CFR 1.143).

6. Claims 1-25 are pending. Claims 3-11, and 16-21, drawn to non-elected inventions, are withdrawn from consideration. Claims 1, 2, 12-15 and 23-25 are examined on the merits.

Claim Rejections - 35 USC § 112

7. Claims 2 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite because of recitations that appear in parentheses, for example, the phrase "uterine cancers (carcinoma of the cervix, endometrial carcinoma, and leiomyoma)". Does this mean that what is in parentheses are examples of different types of uterine cancers, or is the phrase "uterine cancer" limited to what is in the parentheses?

Claim 15 is indefinite because of the phrase "or progeny thereof". The claim is unclear because this phrase is open to interpretation. Do these progeny exist already (i.e. at the time of filing)? Does this claim read on mutated strains of the deposited cell line, which mutants may be created in the future?

8. Claims 1, 2, 12-14 and 23-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific monoclonal antibody, PIP, which is secreted by the hybridoma cell line ATCC No. PTA-4220, does not reasonably provide enablement for any antibody that binds to "PIPA", and antigen that is characterized only by name and as a GPI-linked cell surface protein having a molecular weight 45-50 kD. Additionally, the specification does not reasonably provide enablement for agents that bind PIPA and prevent its interaction with its ligand; or for modulators of PIPA. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The disclosure of the specification does not contain an adequate written description, examples, or guidance whereby, any antibody that binds to an antigen characterized only as "PIPA" could be placed into the hands of the skilled artisan with a reasonable expectation of success without requiring undue experimentation. Furthermore, the specification does not

contain an adequate written description, examples, or guidance whereby, an agent or a modulator that blocks the interaction between PIPA and a PIPA binding partner could be placed into the hands of the skilled artisan with a reasonable expectation of success without requiring undue experimentation

Factors to be considered in determining whether undue experimentation would be required to practice the full scope of the claimed inventions are: 1) quantity of experimentation necessary; 2) the amount of direction or guidance presented in the specification; 3) the presence or absence of working examples; 4) the nature of the invention; 5) the state of the prior art; 6) the relative skill of those in the art; 7) the predictability or unpredictability of the art; and 8) the breadth of the claims. See In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

The specification fails to define the scope of the term "PIPA". The specification teaches that a specific monoclonal antibody, "PIP" binds to PIPA which is an antigen that is 45-50 kD and is GPI-linked and found on the cell surface of some cancer cells. However, the specification fails to teach that phrase "PIPA" is limited to only this protein that is bound by PIP. Therefore, the claims read on antibodies that bind to variants of PIPA, such variants including, for example, deletions from, or insertions or substitutions of residues within PIPA.

Furthermore, the study of the relationship between the primary amino acid sequence and protein function is highly unpredictable. Bowie et al (Science, 247: 1306-1310, 1990) teaches that while it is known that many amino acid substitutions are possible in any given protein, the position with the protein sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Burgess et al (J. Cell Biology, 111 : 2129-2138, 1990) teaches that replacement of a single lysine residue at position 118 of acidic

fibroblast growth factor by glutamic acid led to the substantial loss of heparin binding, receptor binding and biological activity of the protein. Lazar et al (Molecular and Cellular Biology, 8: 1247-1252, 1988) teaches that replacement of aspartic acid at position 47 with alanine or asparagines does not affect biological activity while replacement with serine or glutamic acid sharply reduces the biological activity of the protein. These references demonstrate that even a single amino acid substitution will often dramatically affect the biological activity and characteristics of a protein. Because of the unpredictability of the protein arts, the skilled artisan cannot make and use the broad genus of antibodies that bind to "PIPA" recited in the claims because such a genus encompasses antibodies that bind to antigens having an unlimited and thereby infinite plurality of amino acid substitutions, deletions, additions, or combinations thereof, as compared with the working embodiments.

The instant method claims encompass all types and manner of antibodies that bind to an antigen identified a "PIPA", which is not characterized by amino acid sequence, and further the specification fails to define the scope of the term "PIPA". Thus, the term "PIPA" includes every and all "PIPA" from every animal species on earth and every possible allelic variant of the foregoing, which variants are not envisioned or adequately described by the disclosure. The working embodiments of the specification provide a single monoclonal antibody, which is a minor portion of a very broad genus of antibodies, and does not teach or support the majority of the genus as a whole. Additionally, the claims (23-24) encompass non-antibody compounds that block the binding of PIPA and a PIPA binding partner, or is a ligand of PIPA. One of skill in the art would have to engage in further experimentation to learn how to use many of the claimed antibodies, which may bind to proteins that are not similar in function or structure to the antigen

that is bound by the one disclosed antibody. Furthermore, the specification fails to disclose any information regarding PIPA ligands. Therefore, such further experimentation would be undue experimentation, because it would constitute experimentation on the claimed invention to discover uses and the biological function of PIPA, and to discover a ligand for PIPA.

9. Claims 1, 2, 12-14 and 23-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that the specification fails to describe the antigen PIPA in sufficient detail so that one of skill in the art would understand that applicant was in possession of the genus of antibodies that bind to PIPA.

The claims are drawn to a genus of antibodies (and pharmaceutical compositions comprising antibodies, and to agents that bind or modulate PIPA) that bind to PIPA. Additionally, claims 23-25 are drawn to antibodies and non-antibody molecules that have the function of blocking the interaction between PIPA and its ligand, which has not yet been discovered. For a claim drawn to a genus, the written description requirement may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant, identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A "representative number of species" means that the species, which are adequately described, are

representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus (see Official Gazette 1241 OG 174, January 30, 2001).

The specification discloses a hybridoma that produces a monoclonal antibody, PIP, which binds to antigen, PIPA. The specification discloses that PIPA is a protein that is a GPI-linked cell surface glycoprotein, and has a molecular weight of between 45 to 50 kD. The disclosure of PIP, a specific monoclonal antibody, is not sufficient to describe the genus of anti-PIPA antibodies, or sufficient to describe PIPA, because PIP is not representative of all of the different species of antibodies that bind to PIPA. Additionally, the genus of antibodies is quite large, because the specification fails to define the term "PIPA". Thus, the term "PIPA" includes every and all "PIPA" from every animal species on earth and every possible allelic variant of the foregoing, which variants are not envisioned or adequately described by the disclosure. The genus of antibodies that bind to PIPA encompasses antibodies that bind to any epitope on PIPA, which includes the protein bound by PIP as well as the above-mentioned variants, whereas PIP binds to one specific epitope that is not representative of the genus of epitopes encompassed in the structure of PIPA. Furthermore, the disclosure of a specific antibody that binds PIPA is not adequate description for a ligand for PIPA or for an antibody or non-antibody molecule that blocks interaction between PIPA and its putative ligand. Therefore, one of skill in the art would not recognize the applicants were in possession of the genus of claimed antibodies, claimed agents or claimed modulators.

10. Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that the specification fails to provide a description of the progeny of the cell line deposited as ATCC No. PTA-4220.

The term "progeny" implies that claim 15 includes within its scope, cell lines that are yet to be isolated and that are somehow different from the cell line that is deposited as ATCC No. PTA-4220. The only description provided by the specification is the mention of the progeny in the claims, and a brief mention in the disclosure at page 5, paragraph 0014. Because the progeny are possibly materially different cell lines and because they do not appear to have existed at the time of filing, one of skill in the art would not understand that applicant was in possession of the claimed inventions to the extent the claimed inventions read on progeny of a cell line deposited as ATCC No. PTA-4220.

11. Claims 12-14 and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pharmaceutical compositions comprising the specific antibody secreted by the hybidoma, ATCC No. PTA-4220, wherein the antibody is conjugated or bound to a therapeutic agent or toxin, does not reasonably provide enablement for pharmaceutical composition comprising any antibody to PIPA or comprising the specific antibody secreted by the hybridoma ATCC No. PTA-4220, wherein the specific antibody is not conjugated or bound to a therapeutic agent or toxin. The specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The basis for this rejection is that the intended use of the full scope of the claimed pharmaceutical compositions is not enabled by the disclosure of the specification.

Factors to be considered in determining whether undue experimentation would be required to practice the full scope of the claimed inventions are: 1) quantity of experimentation necessary; 2) the amount of direction or guidance presented in the specification; 3) the presence or absence of working examples; 4) the nature of the invention; 5) the state of the prior art; 6) the relative skill of those in the art; 7) the predictability or unpredictability of the art; and 8) the breadth of the claims. See In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

The claimed pharmaceutical compositions comprise an antibody that binds to PIPA, and encompass a specific monoclonal antibody secreted by a cell line identified as ATCC No. PTA-4220. Additionally the claimed pharmaceutical compositions comprise antibodies conjugated to therapeutic agents or toxins, or to compositions comprising an antibody and further comprising an additional therapeutic moiety. Claim 24, while include antibodies within its scope, also includes any molecule that blocks the interaction between PIPA and its putative binding partner.

The specification teaches that the antibody that is secreted by the cell line identified as ATCC No. PTA-4220, while it binds to the ovarian cancer cell line OV90, fails to inhibit proliferation of this cell line. The specification does teach that proliferation is reduced by 50% of OV90 cells that are treated with Mab-ZAP, which comprises a monoclonal antibody that binds to the specific antibody secreted by ATCC No. PTA-4220 conjugated to saporin. Internalization of the PIPA with the complex of PIPA antibody and Mab-ZAP results in reduced cell

proliferation because of the activity of the saporin moiety, and not because of the activity of the anti-PIPA antibody.

The prior art teaches that methods of treating cancer with antibodies is unpredictable (see Dickman, S., Science, 280: page 1196-1197, 1998). Dickman teaches that one aspect of failure with antibody therapeutics is that results from mouse experiments do not replicate in human experiments (see page 1196, 1st column of article). In the instant case, the data provided is in vitro data demonstrating that the specific antibody that is produced by the cell line ATCC No. PTA-4220 by itself has no effect on proliferation. Therefore, it does not appear that the antigen to which this specific antibody binds is an antigen that is associated with proliferation of cancer cells. The basis for this specific antibody's pharmaceutical use is that this specific antibody is internalized by cells expressing the antigen to which this antibody binds, and therefore, the antibody may be used to deliver toxins to inside of the cell.

Thus, while the specification does provide teachings that an antibody produced by cell line ATCC No. PTA-4220 may be used to bind a chemotherapeutic agent such as Mab-ZAP, and then because the antibody is internalized will cause a decrease in proliferation of the targeted cancer cell, this teaching does not extrapolate to the use any antibody that binds PIPA, because the internalization may be due to the specific epitope to which the specific antibody binds. Furthermore, this teaching does not extrapolate to the use of the specific antibody when it is not used as a delivery vehicle, because the specification clearly shows that the antibody by itself has no effect on proliferation of OV-90 cancer cells. Finally, with respect to claim 24, which reads on molecules in addition to antibodies that block the interaction between PIPA and a PIPA binding partner, the teaching of a specific monoclonal antibody, which has not been shown to

have such a function, does not provide support or put into the hands of a skilled artisan, antibodies or other molecules that have such a function, because the one example of a specific monoclonal antibody has not been shown to have such a function, and furthermore, the specification fails to disclose the nature of the PIPA binding partner.

The claimed inventions are not commensurate in scope with the teachings of the specification, because the claimed pharmaceutical compositions comprise unconjugated antibodies that bind any epitope of PIPA, and also encompass non-antibody and antibody molecules that inhibit binding between PIPA and a PIPA binding partner. In contrast, the specification narrowly teaches that a specific antibody that binds PIPA, which antibody happens to be internalized, causes a reduction in proliferation only due to the internalization of a toxic substance that is complexed with the antibody, and that the antibody itself apparently has no effect on cell proliferation. Therefore, further experimentation would have to be conducted on the claimed pharmaceutical compositions to practice the full scope of the invention. This further experimentation is undue experimentation because it would involve discovering the biological function of PIPA, if any, in cancer; and would also require research to discover the PIPA binding partner, and whether the interaction between the two plays a role in cancer.

12. Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not set forth in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 15 is drawn to a specific cell line, ATCC No. PTA-4220. The specification teaches that this cell line is deposited at the ATCC, however, it is not clear that this cell line is

freely available to the public. Applicant is required to amend the specification to recite the accession number of the deposit, the date of deposit, a description of the deposited biological material, and the name and address of the depository. See In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

Furthermore, if the deposit is made under the provision of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposits have been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the Budapest Treaty as the treaty leaves this specific matter to the discretion of each member state.

If the deposits are not made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809 regarding availability of deposits, assurance of compliance is required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit, over his or her signature and registration number, averring:

(a) that all restrictions on the availability to the public of the material will be irrevocably removed upon the granting of a patent.

(b) that the material has been deposited under conditions that ensure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 35 CFR 1.14 and 35 USC 122.

(c) that the deposited material will be stored with all care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case at least thirty (30) years after the date of a deposit or for the enforceable life of the patent, whichever is longer.

(d) that the duty to replace the deposit should the depository be unable to furnish a sample when requested due to the condition of the deposit.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 2, 12, 13, and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith (Smith, G.M. et al., Journal of Clinical Immunology, 17(6): 502-509, 1997; cited in the IDS).

Claims 1 and 2 are drawn to antibodies that bind PIPA. Claims 12 and 13 are drawn to pharmaceutical compositions comprising an antibody that binds PIPA with a pharmaceutically

acceptable carrier. Claims 23-24 are drawn to agents that can bind to PIPA and the pharmaceutical compositions thereof. Claim 25 is drawn to a modulator of PIPA that may bind to PIPA.

Smith teaches an antibody that binds to CD48, which is a protein that is 47kD and is GPI-linked glycoprotein, that is expressed in lymphoid malignancies (see abstract and page 502, 2nd column; and page 503, 1st-2nd column). Because PIPA is characterized in the specification as a GPI-linked protein present on various tumor cells and having the molecular weight of between 45-50 kD, it appears that an antibody that binds to CD48 is the same as an antibody that binds to PIPA. Therefore, Smith teaches the claimed inventions.

14. Claims 1, 2, 12, 13, and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/35614 (published 2 October 1997).

WO 97/35614 teaches antibodies and pharmaceutical compositions thereof, that bind to CD48. The antibodies may be conjugated to toxic agents or radiopharmaceuticals (page 2, line 26- page 3 line 30. Because PIPA is characterized in the specification as a GPI-linked protein present on various tumor cells and having the molecular weight of between 45-50 kD, it appears that an antibody that binds to CD48 is the same as an antibody that binds to PIPA. Therefore, WO 97/35614 teaches antibodies, pharmaceutical compositions, binding agents and PIPA modulators that are the same as that claimed.

15. Claims 1, 23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Ianelli (Ianelli, C.J. et al, The Journal of Immunology, 159: 3910-3920, 1997).

Ianelli teaches antibodies that bind to CD48 (see page 3913, 2nd column). Ianelli also teaches a ligand for CD48, and antibodies that bind to that ligand that block binding between CD48 and the ligand (page 3913-3914, bridging paragraph). Ianelli also teaches a soluble CD48 fusion protein useful for screening for CD48 ligand bearing cells (page 3912-3913. Because PIPA is characterized in the specification as a GPI-linked protein present on various tumor cells and having the molecular weight of between 45-50 kD, it appears that an antibody that binds to CD48 is the same as an antibody that binds to PIPA. Thus, Ianelli teaches the claimed inventions.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official

Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
June 22, 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER